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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,510	02/08/2002	Edwin Clark	MRI-027	3451

959 7590 05/03/2004

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EXAMINER	
RAWLINGS, STEPHEN L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,510	CLARK ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-69 are pending in the application and are currently subject to restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-14, drawn to a method for determining whether an agent can be used to reduce the growth of a tumor, wherein said method comprises obtaining a sample of tumor cells and determining whether the tumor cells express one or more sensitivity markers, classified in class 435, subclass 6 or subclass 7.1.

Group II. Claims 15-28, drawn to a method for determining whether an agent can be used to reduce the growth of a tumor, wherein said method comprises obtaining a sample of tumor cells and determining whether the tumor cells express one or more resistance markers, classified in class 435, subclass 6 or subclass 7.1.

Group III. Claims 29-36, drawn to a method for determining whether an agent can be used to reduce the growth of a tumor, wherein said method comprises obtaining a sample of tumor cells, exposing the tumor cells to one or more agents, and determining whether the tumor cells express one or more sensitivity markers, classified in class 435, subclass 6 or subclass 7.1.

Group IV. Claims 37-44, drawn to a method for determining whether an agent can be used to reduce the growth of a tumor, wherein said method comprises obtaining a sample of tumor cells, exposing the tumor cells to one or more agents, and determining whether the tumor cells express one or more resistance markers, classified in class 435, subclass 6 or subclass 7.1.

Group V. Claims 45-56, drawn to a method for determining treatment with an anti-cancer agent should be continued in a cancer patient, wherein said method comprises obtaining two or more samples comprising tumor cells from a patient during the course of anti-cancer treatment and determining whether the tumor cells express one or more sensitivity markers, classified in class 435, subclass 6 or subclass 7.1.

Group VI. Claims 57-68, drawn to a method for determining treatment with an anti-cancer agent should be continued in a cancer patient, wherein said method comprises obtaining two or more samples comprising tumor cells from a patient during the course of anti-cancer treatment and determining whether the tumor cells express one or more resistance markers, classified in class 435, subclass 6 or subclass 7.1.

Group VII. Claim 69, insofar as the claim is drawn to a method for reducing the growth rate of cancer in a patient, wherein said method comprises administering to a patient with cancer an agent identified by the method of claim 1 or 8, classified in class 424 or 514, but which cannot be fully classified, since the chemical and biologic nature of the agent is not specified.

Group VIII. Claim 69, insofar as the claim is drawn to a method for reducing the growth rate of cancer in a patient, wherein said method comprises administering to a patient with cancer an agent identified by the method of claim 15 or 22, classified in class 424 or 514, but which cannot be fully classified, since the chemical and biologic nature of the agent is not specified.

Group IX. Claim 69, insofar as the claim is drawn to a method for reducing the growth rate of cancer in a patient, wherein said method comprises administering to a patient with cancer an agent identified by the method of claim 29 or 33,

classified in class 424 or 514, but which cannot be fully classified, since the chemical and biologic nature of the agent is not specified.

Group X. Claim 69, insofar as the claim is drawn to a method for reducing the growth rate of cancer in a patient, wherein said method comprises administering to a patient with cancer an agent identified by the method of claim 37 or 41, classified in class 424 or 514, but which cannot be fully classified, since the chemical and biologic nature of the agent is not specified.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I-X are distinct, each from the other, because the recited processes of the claimed inventions in each group are different, as the processes comprise a different or unique set of steps and are materially different or unique. In addition, the inventions of groups I and II are methods comprising determining whether a tumor cell expresses one or more markers, so as to make *a priori* determination of whether or not an agent can be used to reduce the growth of a tumor; whereas the inventions of group III and IV are methods comprising exposing tumor cells to one or more agents, which does or does not reduce the growth of a tumor, and determining how the expression of one or more markers is affected by the exposure, so as to develop a signature expression pattern of one or markers, which is indicative of tumors that are or are not sensitive to the effects of the agent or agents; and the inventions of group V and VI are methods comprising monitoring the effects of an anticancer treatment by comparing the expression of one or markers in samples acquired from a patient at different time points during the course of treatment, so as to determine whether or not the treatment should be continued. In contrast, the inventions of groups VII-X are different processes for reducing the growth rate of cancer in a patient, each of which comprises distinct steps. Accordingly, the objective to practicing the claimed methods in each group differs, the outcome or endpoint determined or measured in practicing the claimed methods in each group differs, and the probability of success in practicing the claimed methods in each group differs, such that each group has achieved a different status in the art and the

examination of any one group would require considerations not required for examination of any other.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Each of groups I-X is further subject to a restriction of patentably distinct species of invention:

(a) In each of groups I-X, the claims are drawn to patentably distinct species of invention, wherein the one or more markers to which the claims refer is selected from those recited in Tables 1-6 of the specification.

It is recognized that the claims in each of groups I-X specify a process comprising determining the presence, or the expression level of at least one marker. Each marker is a different product, having a different sequence and requiring a unique search that is not required of any of the other markers. In addition, the search of any single marker will not provide adequate information regarding any of the other markers. Therefore, to the extent that the claims in each of groups I-X are drawn to a process comprising determining the presence, or the expression level of any one marker or any one combination of markers selected from Tables 1-6 of the specification, the claims are drawn to patentably distinct inventions.

Accordingly, Applicant is required under 35 U.S.C. 121 to specifically elect a single disclosed species of invention by specifically identifying the at least one marker from the markers recited in Tables 1-6 of the specification to which the claims of the elected group will be drawn for prosecution on the merits and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that the recitation of one novel and nonobvious marker within a specifically claimed combination of one or more markers would

render the combination allowable over the prior art, but not necessarily over 35 U.S.C. §§ 101 and 112.

(b) Regarding groups III, IV, IX, and X, the claims are drawn to patentably distinct species of invention, wherein the one or more agents to which the claims refer is selected from those agents disclosed in the specification.

It is recognized that the claims in each of groups III, IV, IX, and X specify a process comprising exposing the tumor cells to at least one agent. Each agent is a different product, having a different structure and/or mode of action and requiring a unique search that is not required of any of the other agents. In addition, the search of any single agent will not provide adequate information regarding any of the other agents. Therefore, to the extent that the claims in each of groups III, IV, IX, and X are drawn to a process comprising exposing the tumor cells to at least any one agent selected from those agents disclosed in the specification, the claims are drawn to patentably distinct inventions.

Accordingly, Applicant is required under 35 U.S.C. 121 to specifically elect a single disclosed species of invention by specifically identifying the at least one agent from those disclosed in the specification to which the claims of the elected group will be drawn for prosecution on the merits and to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner notes that the recitation of one novel and nonobvious agent within a specifically claimed combination of one or more agents would render the combination allowable over the prior art, but not necessarily over 35 U.S.C. §§ 101 and 112.

(c) Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
April 20, 2004

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SUPERVISORY PATENT EXAMINER
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